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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/857,485	06/06/2001	Steven Leigh	032553-011	5205
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/26/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,485

Applicant(s)

Leigh

Examiner

Gollamudi Kishore

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☒ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The preliminary amendment dated 6-6-01 is acknowledged.

Claims included in the prosecution are 1-38.

Specification

1. The disclosure is objected to because of the following informalities: There is no Brief description of the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is being conveyed by ‘hardening said lipid or lipids’ as recited in claim 1?

Does it mean solidifying a liquid lipid?

What is a generally regarded as safe status as recited in claims 2 and 32? Regarded as safe by whom?

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What is being conveyed by ‘membrane lipid’ in claims 3 and 4? Is this lipid present in addition to the lipid in claim 1 and in the form of a membrane?

Is the ‘enzyme digested lecithin’ recited in claim 5 is in addition to the lipids in claim 1?

Proper Markush format with the expression ‘selected from the group consisting of’ and the use of the terms either ‘and’ OR ‘or’ only before the last Markush member should be followed in claim 11.

‘another polyol ester’ in claim 14 is deemed to be indefinite since ‘another’ is not a positive expression.

It is unclear whether the limitation in parenthesis in claim 27 is indeed the limitation.

‘said’ is misspelt in claim 29.

Aren’t starches and celluloses natural polysaccharides? (Claim 32).

It is unclear what ‘partly synthetic’ in claim 36 represents. If a compound is modified from natural sources chemically, then it is a synthetic compound.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 7-17, 33-34 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Ke (5,221,696).

Ke discloses compositions containing an active agent, a lysolipid and a polymer which is either a gum or carrageenan or a cellulose derivative (note the abstract, Examples and claims).

6. Claims 1-4, 8-9, 12, 14-18, 26-29, and 31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 181 287 of record.

EP discloses lyophilized compositions containing a steroidal active agent and a mixture of a diacyl lipid (phospholipid) and a monoacyl lipid (ascorbylpalmitate) and a polymer (carbowax, polyethylene glycol) (note the entire patent, Example 2 on page 7 in particular).

This rejection will be reconsidered upon the submission of an English translation.

7. Claims 1-5, 9-10, 12-18, 26-31, and 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 635 218 of record.

EP 218 discloses a freeze-dried product of enzymatically treated lecithin (contains lysolecithin) and a polymeric material (casein). EP also teaches that lysophospholipids are preferable (note the abstract, pages 5-8 and Examples, examples on page 9 and 19 in particular). The compositions are in the form a tablet or a capsule, powders, granules and fine granules (note page 7, lines 53-54).

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8. Claims 1-4, 8-9, 11-12, 14-19, 23-29, 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 195 31 277 of record.

DE teaches a combination of an active agent, mono and diglycerides and a polymer (hydroxypropylcellulose) (note pages 2-5).

The examiner will reconsider this rejection upon submission of an English translation.

9. Claims 1-5, 7-12, 14-15, 26-28, and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 6245719 of record.

JP teaches a spray dried preparation containing fatty acid esters of either glycerine or sucrose, lecithin and starch (note the abstract and the English translation).

10. Claims 1-3, 7-17, 33-34 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Leigh 5,141,674.

Leigh discloses liposomal powders containing a hydrophobic drug and a lipophilic medium and a polymer such as starch and dextran. The liposomes are made of glycolipids or mono and dialkyl polyoxyethylene derivative or two grades of soybean lecithin (note the abstract, col. 3, line 13 through col. 4, line 25, Example IV and claims). It is known in the art that commercially available lecithins contain lysophospholipids. The examiner cites US 6,303,803 in this context. The examiner also points out that sphingosine (monoacyl compound) containing a sugar residue is a glycolipid.

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Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 6, and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 635 218 cited above.

It is unclear from EP whether the amounts of the lipid corresponds to instant amounts expressed on molar basis. Assuming the amounts are different, in the absence of showing unexpected results, it is deemed obvious to manipulate the basic teachings of EP to obtain the best possible results. EP does not disclose the specific particle sizes. However, from the reference's teachings of granules and fine granules, it would have been obvious to one of ordinary skill in the art that the granules can be of any sizes including the claimed ranges, depending upon the purpose for which they are used. EP does not disclose specific drugs; it is deemed obvious to one of ordinary skill in the art to use any drug in EP with a reasonable expectation of success.

11. Claims 1-28 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leigh (5,141,674) in view of Huang (5,043,164), Baumann (5,009,956) individually or in combination.

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Leigh as pointed out above, discloses liposomal powders containing a polymer and a hydrophobic active agent. The liposomes are also made from two grades of lecithin (note the abstract, col. 3, line 13 through col. 4, line 25, Example IV and claims). Although as pointed out above, Lecithins are known to be impure mixtures of phospholipids including lyso compounds, Leigh does not specifically teach lysophospholipids.

Huang teaches that micelle forming amphiphiles, lysophospholipids stabilize the liposomes (note the claims).

Baumann teaches lysophospholipids prevent liposomal cleavage by phospholipase A and stabilize the liposomes (note the abstract and claims).

The use of lysolipids or the addition of lysolipids in the teachings of Leigh would have been obvious to one of ordinary skill in the art since Huang and Baumann teach the advantages of using the lysolipids. The criticality of specific drugs recited in instant claims is not readily apparent to the examiner since the novelty of the composition rests in the components it would have been obvious to one of ordinary skill in the art to use any drug with a reasonable expectation of success.

UK 9827006.9 (priority document) has not been received.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

August 21, 2002